

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. 2003P–0266]**

### **Determination That LOVENOX (Enoxaparin Sodium) 90 Milligrams/0.6 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its determination that LOVENOX (enoxaparin sodium) 90 milligrams (mg)/0.6 milliliter (mL) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for enoxaparin sodium 90 mg/0.6 mL.

**FOR FURTHER INFORMATION CONTACT:** Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not

have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is generally known as the “Orange Book.” Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

LOVENOX (enoxaparin sodium) 90 mg/0.6 mL, is the subject of approved NDA 20–164 held by Aventis Pharmaceuticals, Inc. (Aventis). LOVENOX (enoxaparin sodium) 90 mg/0.6 mL, approved June 2, 2000, is an anticoagulant indicated for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism. Aventis never marketed the 90mg/0.6 mL presentation of LOVENOX. On June 10, 2003, Olsson, Frank and Weeda, P.C. submitted a citizen petition (Docket No. 2003P–0266) under § 314.161 and 21 CFR 10.21(a) and 10.30, requesting that the agency determine whether LOVENOX (enoxaparin sodium) 90 mg/0.6 mL was withdrawn from sale for reasons of

safety or effectiveness. The agency has determined that, for purposes of § 314.161(a) and (c), never marketing an approved drug product is equivalent to withdrawing the drug from sale.

The agency has determined that Aventis' LOVENOX (enoxaparin sodium) 90 mg/0.6 mL was not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that Aventis continues to market other presentations of LOVENOX that are the same concentration as LOVENOX 90 mg/0.6 mL. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, Aventis' LOVENOX (enoxaparin sodium) 90 mg/0.6 mL was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list LOVENOX (enoxaparin sodium) 90 mg/0.6 mL in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to LOVENOX (enoxaparin sodium) 90 mg/0.6 mL may be approved by the agency.

Dated: February 27, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

**BILLING CODE 4160-01-S**